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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,462	03/16/2004	Yougandh Chitre	A04P1025	4009
36802	7590	09/01/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			PATEL, JOY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/802,462

Applicant(s)

CHITRE ET AL.

Examiner

Joy P. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/16/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because elements 54 and 52 point to the same conductor in figure 5 and because elements 52A and 54A point to the same conductor in figure 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show element 112 as described in the specification. Any structural detail that is

essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to

the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 8, 10, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Littman et al (US 6,141,576).
5. In regard to claims 1 and 2, Littmann discloses, "The catheter or guidewire preferably has a tubular shaft formed of braided strands which include a plurality of insulated conductors, which are electrically connected to bipolar electrodes" (Abstract, lines 6-9). It is noted that the term co-extruded defines a product by process. Since the resulting structure of the process in a product by process type claim is the only distinguishing feature given patentable weight, Littman et al. is considered to meet such limitation in that the lead is coated with insulation.
6. In regard to claims 8 and 14, Littmann discloses, "Electrical signals from the patient's heart are received by the one or more electrode pairs on the distal section in bipolar mode and transmitted through the electrical conductors attached to the individual electrodes to multipin connectors on the proximal ends

of the shafts" (Column 3, lines 12-16). Littmann further discloses, "The distal section (12) of the shaft (11) is provided with a plurality of bipolar electrode pairs (16), each pair of which includes electrodes (17) and (18)" (Column 4, lines 24-28). See also figures 1 and 2. Figures 1 and 2 depict electrode pairs (16) on the distal section (12) of the shaft that are proximally spaced from one another.

7. In regard to claim 10, Littmann discloses, "The elongated device of the invention may also be in the form of a catheter, which has an elongated inner lumen extending from the proximal end to a discharge or guidewire port in the distal end of the device" (Column 2, lines 53-56). Littmann further discloses, "In one presently preferred embodiment, the inner lumen of the catheter form of the device of the invention is configured to allow the passage therethrough of a conventional guidewire...." (Column 2, lines 59-63). Littmann also discloses, "The outer jacket may be a thermoplastic fluoropolymer such as THV, which is available from the 3M Corporation" (Column 6, lines 33-35). It is known that THV is a highly flexible, insulative material.
8. In regard to claim 15, Littmann discloses, "The insulation on separate conductors is exposed under each of the sensing electrodes so that an electrical connection can be made" (Column 2, lines 17-19).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann et al (US 6,141,576) in view of Cobain et al (US 5,796,044). Littmann, as discussed above, teaches a conductor composed of a copper wire, which are provided with a "...thin insulated jacket or coating of polyimide..." (Column 6, line 32). However it is common in the art to use other materials, such as PTFE (polytetrafluoroethylene) or ETFE, both of which are fluoropolymers. Cobain discloses, "Effective insulation of the coiled wire conductor surface with a PTFE or ETFE coating would allow the use of these polyurethane materials in lead body outer sheaths..." (Column 3, lines 40-42). Cobain also discloses, "The typically used composite conductive material wires are formed with a silver core, to provide increased conductivity, clad with MP35N alloy or surgical grade stainless steel...in a drawn brazed stranded (DBS) or drawn filled tube (DFT) fabrication process well known in the art..." (Column 2, lines 41-46). Therefore, it would have been obvious to one of ordinary skill in the art to modify the Littmann device to utilize a commonly used conductive material, such as MP35N. It would also have been obvious to one of ordinary skill in the art to modify the Littmann

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device to utilize either PTFE or ETFE, both common insulators in the art, as the insulative material for the Littmann device.

10. Claims 9, 11, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann et al (US 6,141,576) in view of Malonek et al (US 2002/0055764 A1).
11. In regard to claim 9, Littmann, as discussed above, teaches electrodes that are proximally spaced from the distal tip electrode. However, Littmann fails to teach a ring electrode proximally spaced from the distal tip electrode. It is common in the art for medical leads to use ring electrodes as can be seen in the lead developed by Malonek. Malonek teaches, "Each sensing electrode (15) (Fig. 13 or 17), in the second or third embodiments, can be constituted by a single ring or by a pair of rings. A transverse cross section of a sensing electrode is shown in FIG 15b" (Paragraph 112, line 5-8). Since Malonek discloses that all of the sensing electrodes can be ring electrodes, electrodes proximally spaced from the distal tip electrode can also have to be ring electrodes. Therefore, it would have been obvious to one of ordinary skill in the art to modify the medical lead of Littmann to have a ring electrode spaced proximally from the distal electrode, since ring electrodes are commonly used in medical leads in the art.
12. In regard to claims 11, 12, and 13, Littmann, as discussed above, teaches a medical lead with an insulative material formed from a thermoplastic fluoropolymer, such as THV. Littmann fails to mention other materials that could be used as an insulative coating on the medical lead. It is common in the art to



use either silicone or polyurethane as a biocompatible insulative material for medical leads as can be seen in the Malonek lead. Malonek teaches, "The proximal carrier shaft portion (70), is made from an insulating material, such as polyurethane (55D) or silicone..." (Paragraph 96, lines 12-14). Malonek further discloses, " The distal carrier shaft portion (50) is similar to the proximal portion (70) and is made from an insulating material, such as polyurethane (55D) or silicone" (Paragraph 97, lines 7-9). Therefore, it would have been obvious for one of ordinary skill in the art to modify the lead of Littmann to use another commonly implemented biocompatible insulator or a combination thereof.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann in view of Sundquist (US 6,934,589). Littmann, as discussed above, teaches, "The elongated device of the invention may also be in the form of a catheter which has an elongated inner lumen extending from the proximal end to a discharge or guidewire port in the distal end of the device" (Column 2, lines 53-56). However, Littmann fails to teach the means by which the guide wire will be inserted into the lumen. It is common in the art to utilize introducer sheaths or catheters in order to place a medical lead. Sundquist teaches, "Another approach to lead placement involves the use of a guidewire that is steered into a desired location within the vasculature. The lead body is then tracked over-the-wire and the wire is withdrawn. According to this design, this guidewire passes through an inner lumen of the lead for an entire length of the lead. (Column 2, lines 47-52). Therefore, it would have been obvious to one of ordinary skill in the


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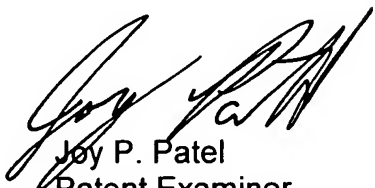
art to utilize an introducer sheath to permit the introduction of the lead into the body.

**Conclusion**

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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